Pericardium Suture Retention Strength

The Challenge:

Determine the Suture Retention Strength of Porcine Pericardium with Different Suture Materials

Background

Suture retention tests are performed on synthetic patches and tubular prostheses to see how closely they replicate native tissue mechanical properties and to determine resistance to failure. Researchers have often utilized allografts and xenografts in tissue repair studies, as they closely mimic the mechanical properties of native tissues and eliminate the need for manufacturing prostheses. Porcine pericardium has widely been used to develop heart valves, cardiac tamponade patches, and tubular vascular grafts. These implantations involve suturing, and retention tests can be performed to determine the appropriate suture material and thickness based on the resulting behavior of the sample.

Meeting the Challenge

A uniaxial TestBench setup consisting of the Bose® Extended Stroke (ES) actuator, a reaction bracket, DMA tensile grips, and a 22 N load cell, were used to determine the suture retention strength and failure mechanics of the pericardium.

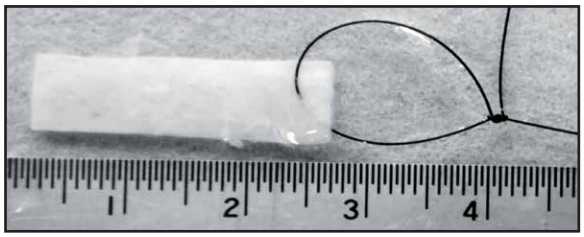

Figure 1 - Pericardium sample prior to testing. Loop of suture was at least 2 mm from end of sample.

Materials

Sixteen (16) porcine pericardium samples (Midwest™ Research Swine) were cut in the same relative orientation and similar dimensions. Nylon and polyester surgical sutures (Ethicon Inc.), of sizes 3-0 and 4-0, were looped once through every sample as shown in Figure 1.

Methods

Suture retention test protocols were adapted from the methods described within the ANSI/AAMI/ISO 7198:1998/2001/(R) 2004 "Cardiovascular implants—Tubular vascular prostheses" [1] standard. In accordance with the standard, samples were sutured at a minimum distance of 2 mm (d_{sut}) from the sample's free end (Figure 1). The ES actuator displacement speed (V_R) was set at 1 mm/sec which falls within the range of rates specified by the standard. Sixteen (16) samples were tested in total. The pericardium sample was gripped in one of the tensile grips which was connected to the load cell mounted to the static reaction bracket. The suture was gripped within the opposing tensile grip and connected to the ES actuator (Figure 2). Once the sample was in place, the reaction bracket was adjusted slightly to impart some pre-tension on the suture-pericardium interface. This preload (L_{pre}) was kept below 0.1 N. Following the preload, a ramp-to-failure test was executed utilizing WinTest® 7.1 software's waveform setup utility.

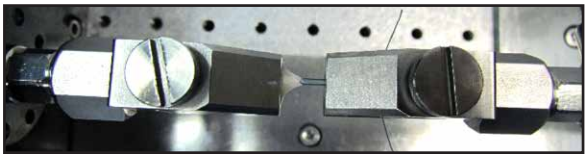

Figure 2 - Loaded sample (top view) with the sample and suture ends gripped by lightweight tensile grips.

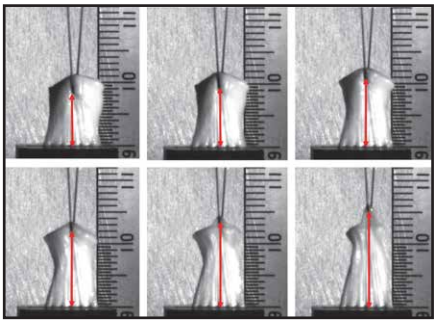

Figure 3 - Time sequence of loaded sample from initial preload to near failure.

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Results

The four groups of suture material were compared based on the sample's mechanical response and the suture retention strength, as outlined in the standard. Reaction forces and loads were measured and presented in units of grams-force in accordance with the standard.

Deformation is shown in terms of the sample's stretch ratio (λ_s), calculated using Equation 1.

$$\lambda_s = \frac{l_o + \Delta l}{l_o} = 1 + \frac{\Delta l}{l_o} = 1 + \frac{d_R}{l_o}$$

Equation 1: Sample's Linear Deformation defined as the ratio between the samples final length ($l_o + \Delta l$) to the inital length (l_o).

The initial length of the sample (l_o) was defined as the distance between the edge of the grip and the suture. The linear change in length (Δl) was substituted by the displacement of the ES actuator (d_R). Samples stretched to 250% of the original length before failure. Given an average initial sample length of 4 mm, displacements between 10 and 12 mm were achieved during testing.

The difference in mechanical response across suture thickness was captured within the loading curves for nylon and polyester (example data in Figure 4). Regardless of the suture material, the 4-0 samples generated higher reaction forces when normalized for the stretch ratio achieved for a given test when compared against the 3-0 suture samples. It is hypothesized that the larger suture diameter distributes the applied force over a larger area resulting in higher forces before failure. In general, the tests with the polyester sutures generated higher forces when normalized for the stretch ratio compared to equivalent diameter nylon sutures (Figure 5).

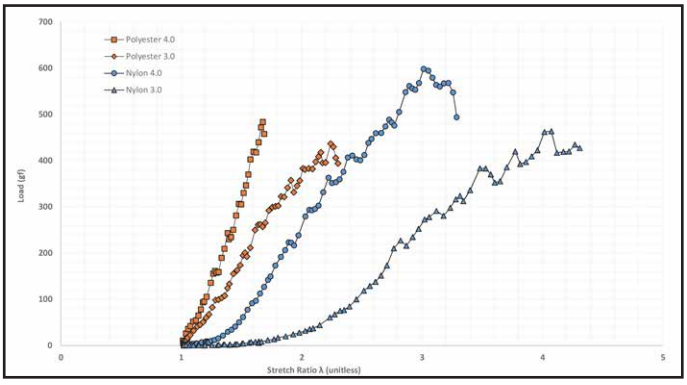

Figure 4 - Suture retention results. The loading curves represent one (1) data series from each group (N3-0, N4-0, P3-0, and P4-0).

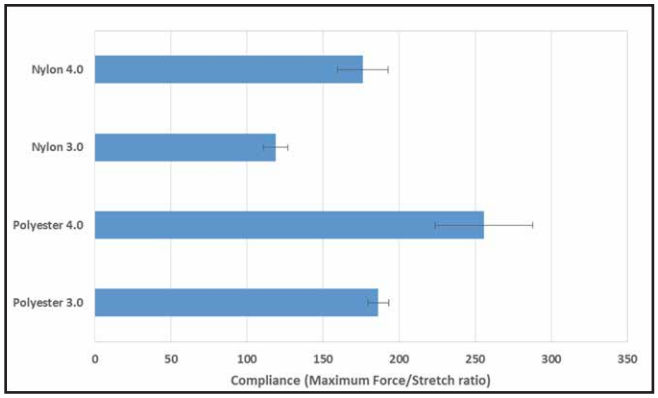

Figure 5 - Comparison of failure forces between suture type and geometry when normalized for stretch ratio.

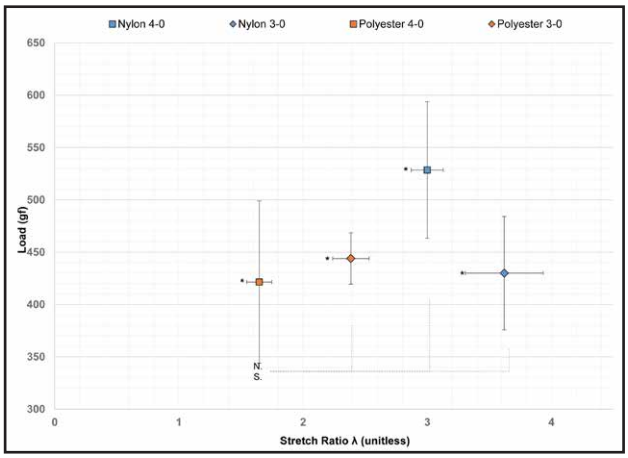

Figure 6 - Failure region of each group delimited by deviation in both stretch ratio and load at failure.

Sample failure region for each group was described on the basis of the deviation in stretch and load at failure (Figure 6). The means of these regions were compared statistically, in accordance with the standard, by implementation of two single-factor ANOVA tests. The analysis yielded a statistical significance in stretch at failure $p < 0.01$ (2E - 7), while no significant difference was observed in the failure load $p > 0.01$ (0.153).

Summary

These experiments demonstrate the suitability of the Bose® TestBench instrument configured with the ES actuator to perform ramp-to-failure tests on elastic materials or constructs, some of which require significant displacements. Suture retention, which is widely used among synthetic and tissue-based products, can be performed with this test instrument to meet appropriate testing standards.

Reference

[1] Cardiovascular implants - Tubular vascular prostheses. Association for the Advancement of Medical Instrumentation, ANSI/AAMI/ISO 7198:1998/2001(R) 2004. Association for the Advancement of Medical Instrumentation, Arlington, VA (1998).

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